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NOTICE OF ALLOWANCE AND FEE(S) DUE

27777 7590 05/04/2010

PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 EXAMINER
GABEL, GAILFNE

ART UNIT PAPER NUMBER

1641 DATE MAILED: 05/04/2010

 APPLICATION NO.
 FILING DATE
 FIRST NAMED INVENTOR
 ATTORNICY DOCKIET NO.
 CONFRMATION NO.

 10/780,399
 02/17/2004
 Galla Chandra Rao
 VDX5060PT2
 1615

TITLE OF INVENTION: ANALYSIS OF CIRCULATING TUMOR CELLS, FRAGMENTS, AND DEBRIS

APPLN, TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	08/04/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THE APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FIEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

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appropriate. All further indicated unless corrects maintenance fee notifica	correspondence includir ed below or directed oth	ng the Patent, advance on herwise in Block 1, by (a	rders and notification of r a) specifying a new corres	naintenance fees wi spondence address;	ill be r and/or	nailed to the current (b) indicating a sepa	correspondence address as trate "FEE ADDRESS" for
CURRENT CORRESPONDENCE ADDRESS (Note: Use Block I for any change of address)				Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.			
	INSON DHNSON N & JOHNSON PLA		Lbe	Cert	ificate	of Mailing or Trans	mission g deposited with the United tt class mail in an envelope above, or being facsimile ate indicated below.
NEW BRUNSW	/ICK, NJ 08933-700	JS					(Depositor's name)
			<u> </u>				(Signature)
							(Date)
APPLICATION NO.	APPLICATION NO. FILING DATE		FIRST NAMED INVENTOR		ATTORNEY DOCKET NO. CON		CONFIRMATION NO.
10/780,399 TITLE OF INVENTION	02/17/2004 I: ANALYSIS OF CIRC	ULATING TUMOR CEL	Galla Chandra Rao LS, FRAGMENTS, AND	DEBRIS	`	/DX5060PT2	1615
APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE	FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0		\$1810	08/04/2010
EXAM	IINER	ART UNIT	CLASS-SUBCLASS]			
GABEL, C	GABEL, GAILENE		435-007230	,			
"Fee Address" ind PTO/SB/47; Rev 03-0 Number is required. 3. ASSIGNEE NAME A	ondence address (or Cha B/122) attached. ication (or "Fee Address 22 or more recent) attach ND RESIDENCE DATA	inge of Correspondence "Indication form and. Use of a Customer A TO BE PRINTED ON 7	2. For printing on the p (I) the names of up to or agents OR, alternative (2) the name of a single registered attorney or a 2 registered patent atto listed, no name will be THE PATENT (print or type data will appear on the p T a substitute for filing an	3 registered patent vely, e firm (having as a agent) and the name meys or agents. If n printed.	attorn membe s of up to name	era 2 o to e is 3	ocument has been filed for
4a. The following fee(s)	iate assignee category or are submitted:		b. Payment of Fee(s): (Plea	Individual Conse first reapply an	rporatio	on or other private gro iously paid issue fee	oup entity Government
Publication Fee (No small entity discount permitted) Advance Order - # of Copies			☐ Payment by credit card. Form PTO-2038 is attached. ☐ The Director is hereby subnorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number (enclose an extra copy of this form).				
	s SMALL ENTITY state	as. See 37 CFR 1.27.	b. Applicant is no lon				
interest as shown by the	records of the United Sta	ites Patent and Trademark	Office.	ne appricant, a regis	ttitu a	ttorney or agent, or tr	e assignee or other party in
Authorized Signature			Date				
Typed or printed name				Registration No.			
This collection of inform an application. Confiden submitting the completes this form and/or suggesti Box 1450, Alexandria, V Alexandria, Virginia 223	nation is required by 37 C tiality is governed by 35 d application form to the ions for reducing this but 'irginia 22313-1450. DC it3-1450.	FR 1.311. The informatic U.S.C. 122 and 37 CFR USPTO. Time will vary rden, should be sent to the ONOT SEND FEES OR	on is required to obtain or r 1.14. This collection is est r depending upon the indiv e Chief Information Office COMPLETED FORMS TO	etain a benefit by th imated to take 12 m idual case. Any cor er, U.S. Patent and 7 D THIS ADDRESS.	e publi inutes nments fradem SENE	c which is to file (and to complete, including on the amount of tir ark Office, U.S. Depo TO: Commissioner	by the USPTO to process) g gathering, preparing, and ne you require to complete artment of Commerce, P.O. for Patents, P.O. Box 1450,

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APPLICATION NO.	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/780,399		02/17/2004	Galla Chandra Rao	VDX5060PT2	1615	
27777	7590	05/04/2010		EXAMINER		
PHILIP S. JOI	PHILIP S. JOHNSON			GABEL, GAILENE		
JOHNSON & JOHNSO			ART UNIT	PAPER NUMBER		
ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003				1641 DATE MAII ED: 05/04/201	0	

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 398 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 398 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

	Application No.	Applicant(s)	
Examiner-Initiated Interview Summary	10/780,399	RAO ET AL.	
Examiner-initiated interview Summary	Examiner	Art Unit	
	GAILENE R. GABEL	1641	
All Participants:	Status of Application:	<u> </u>	
(1) <u>GAILENE R. GABEL</u> .	(3)		
(2) Mr. Joseph Aceto.	(4)		
Date of Interview: 7 April 2010	Time:		
Type of Interview: ⊠ Telephonic □ Video Conference □ Personal (Copy given to: □ Applicant Exhibit Shown or Demonstrated: □ Yes If Yes, provide a brief description: □ No	int's representative)		
Part I.			
Rejection(s) discussed: of record.			
Claims discussed: claims 44-46, 48-55, and 57-61.			
Prior art documents discussed: of record.			
Part II.			
SUBSTANCE OF INTERVIEW DESCRIBING THE GENERAL See Continuation Sheet	RAL NATURE OF WHAT WAS	S DISCUSSED:	
Part III.			
It is not necessary for applicant to provide a separate r directly resulted in the allowance of the application. The of the interview in the Notice of Allowability. It is not necessary for applicant to provide a separate r did not result in resolution of all issues. A brief summar	e examiner will provide a writte ecord of the substance of the	en summary of the substance interview, since the interview	
(A	pplicant/Applicant's Representat	ive Signature – if appropriate)	

Application No. 10/780,399

Continuation of Substance of Interview including description of the general nature of what was discussed: Indicated to Mr. Aceto that the arguments submitted on January 10, 2010 are presuasive; however, they are not reflected or clearly defined in the recited claims so as to be commensurate in scope with the claimed invention. Examiner proposed claim amendments in accordance to Applicant's arguments as supported in Applicant's disclosure; hereo obviating the prior art of record. Claims 44, 53, and 59 were amended to require enrichment, fractionation, selective detection and differential analysis of all of the intact malignant cells, cell fragments, cellular debris, thereof, as well as clusters of malignant cells using the colloidal magnetic nanoparticles having 50–150 nm, immobilized specific antibodies that bind an epitope present in each one of the cell groups, and antibodies that are further directed against a receptor present in the same malignant tumor cells that are of epithelial cell origin, i.e. cytokeratin, so as to obtain a merical proportion of each of the groups of cells whereupon a change in their proportions over time provides indication of change of cancer malignancy in the test subject.